Disclaimer

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DSCSA Pilot Project Program

Participant Results (1)

Program Participant/Speaker *(All partnering entities are not listed)*	**Pilot Project**
Partnership for DSCSA Governance (PDG)/Matthew Price	DSCSA Governance Processes
ICON INDICES Anurag Saxena	Enterprise Serialization Architecture of Point-To-Point Network System
Tracelink Allan Bowyer	DSCSA Traceability with Distributed Ledgers and Digital Recalls Project Proposal
The Optimal Solution Dwight de Vera	The Optimal Solution a Federated Approach to Designing the Interoperable DSCSA
Sanofi Arthi Nagaraj	Product Identifier Verifications by a Contract Manufacturing Organization on behalf of a Manufacturer Authorization Holder
GS1 US Peter Sturtevant	Barcode Readability for DSCSA 2023 Interoperability

We will have a Participant Panel Q&A after the above presentations.

pdg

Partnership for
DSCSA Governance

Advancing Collaborative, Timely Implementation
of DSCSA Interoperability

PDG Governance Pilot Report

FDA DSCSA PILOT PROJECT PROGRAM

December 8, 2020

Partnership for DSCSA Governance (PDG)

A collaborative forum dedicated to developing, advancing, and sustaining an effective and efficient model for interoperable tracing and verification of prescription pharmaceuticals in the U.S.

www.dscsagovernance.com

@DSCSAGovernance

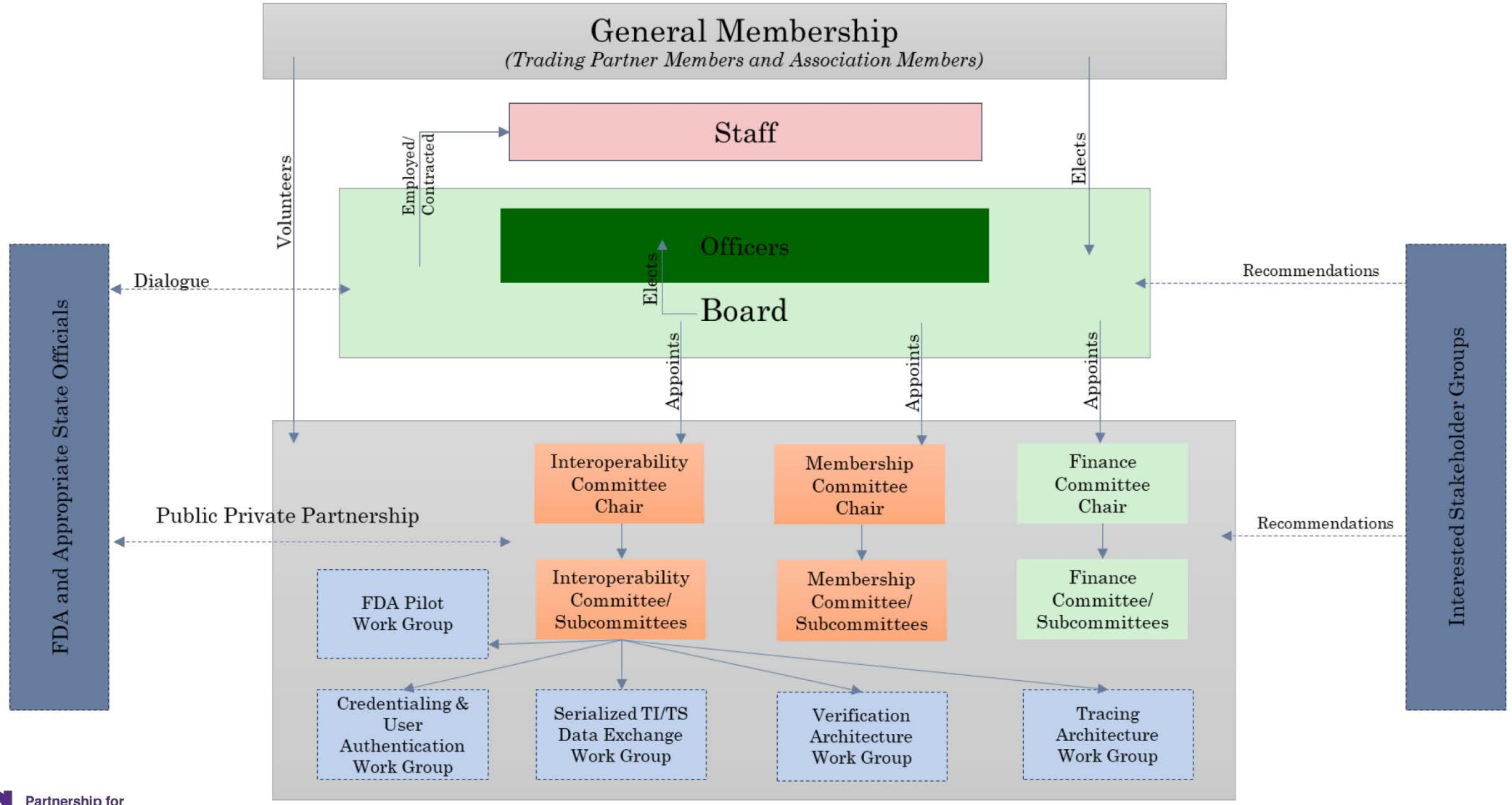
Matthew Price

Vice Chair, PDG Board of Directors

Co-Chair, PDG Pilot Work Group

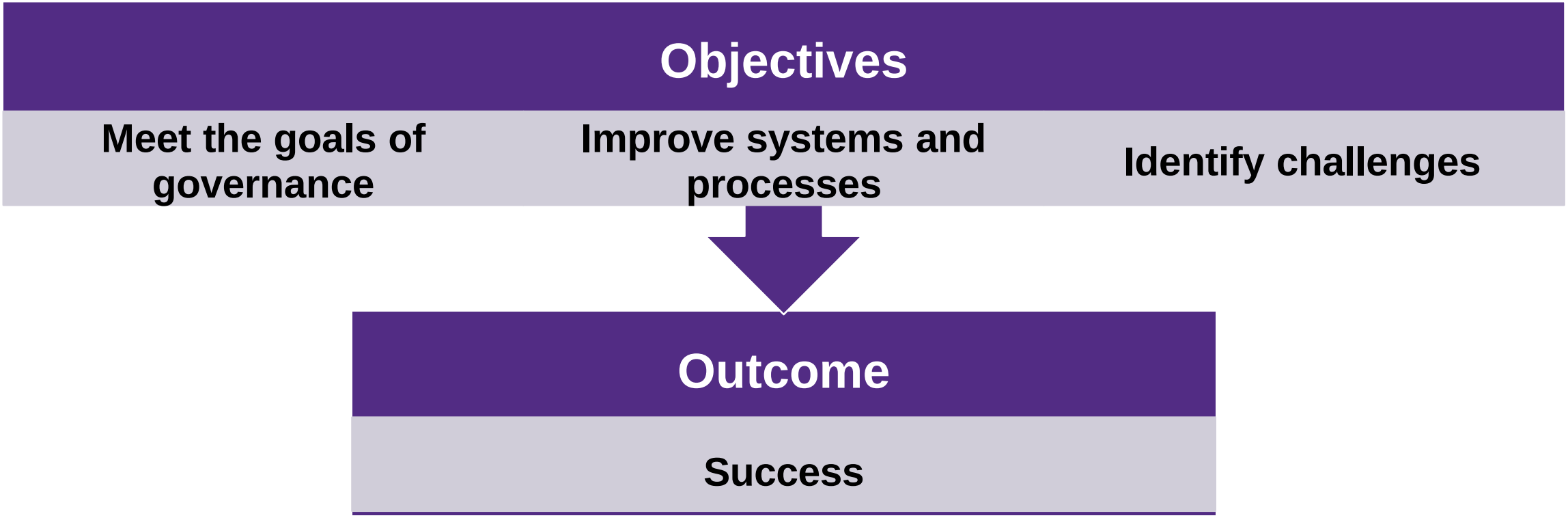
pdg Partnership for DSCSA Governance

PDG Structure



pdg Partnership for DSCSA Governance

Pilot Objectives & Outcome



Partnership for DSCSA Governance

Metrics to Evaluate Governance Structures & Processes

1	Methods/mechanisms for engagement with technical experts
2	Methods/mechanisms for engagement with non-members
3	Methods/mechanisms for engagement with FDA and regulators
4	Incorporation of, and ability to leverage, existing/prior non-PDG efforts
5	Allocation of responsibilities between the Board, Interoperability Committee, and Work Groups
6	Handoffs and relationship between Board, Committees, and Work Groups
7	Board participation
8	Work Group structure and participation
9	Meeting (Board and Committee) cadence and organization
10	Execution of project plan
11	Outputs/documentation

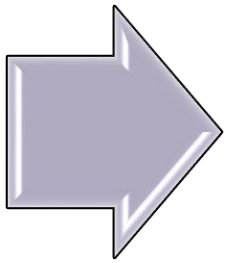
Key Findings

PDG Formation	Sufficient Membership
	Successful Formation
	Sufficient Financial Commitments
Notable Pilot Successes	Meaningful technical participation
	Valuable FDA presence
	Effective use of prior work
	Prior work not seen as binding
	Fair and equal participation
	Fair and balanced decision making
	No major process issues

pdg Partnership for DSCSA Governance

Conclusions & Recommendations

Lesson 1: Ensuring Respect for Output



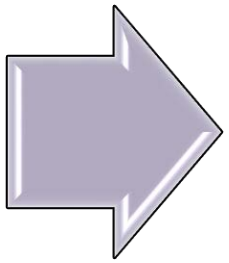
Application:

Refined tools for gaining consensus and eliciting appropriate input

Conclusions & Recommendations

Lesson 2:

Speed vs. Substance



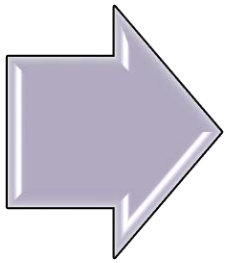
Application:

- Allow for discussions of appropriate depth and detail
- Leverage voting mechanisms, but avoid premature voting
- Manage meeting length and frequency

Conclusions & Recommendations

Lesson 3:

Difficulty of Isolating One Use Case



Application:

- Acknowledge the broader context
- Emphasize cross-work group communication
- Agreed on key principles and assumptions for 2023

2023 DSCSA compliance

Through

Ledger-System

Driven by

INDEX IDENTIFIER AS SERIAL

NDC xxxxxx
SERIAL xxxxxxxxxxxx
LOT xxxx
EXPIRY xxxx

THE DSCSA AND THE ELECTRONIC SYSTEM

The DSCSA establishes the requirements for an electronic, interoperable system, to identify and trace drug products at the package-level that go into effect in 2023.

The 2023 system is going to be populated with

TENS OF TRILLIONS OF RECORDS

A system to identify and trace drug package, **SEARCH for a record** to be processed through such tremendous volume of data.

TIME DELAY and **INACCURACIES** are going to be inevitable**.**

ICON INDICES

Introducing

INDEX-BASED configuration Ledger-system

eliminating search process completely

THEREBY SOLVING

both **TIME DELAY** as well as **INACCURACIES** problems, **permanently**.

LEDGER-SYSTEM – DATA FLOW

NDC xxxxxx
SERIAL 38565657832558727625
LOT xxxx
EXPIRY xxxx

INDEX IDENTIFIER

Ledger-system

MANUFACTURER

NEXT CUSTODIAN

LEDGER ID: XXXX

INDEX	PROUCT IDENTIFIER	CUSTODIAN LEDGER INDEX
172125	XXXXXXXXXXX	75183265194361268366

LEDGER ID: XXXXX

INDEX	PROUCT IDENTIFIER	CUSTODIAN LEDGER INDEX
43125	XXXXXXXXXXX	XXXXXXXXXXXXX

LEDGER-SYSTEM – ATTRIBUTES

ATTRIBUTES	IMPACT
Eliminate search process	Time to response, **absolute minimum**
One Data One Place model leading to Zero Data redundancy	Accuracy, **heightened**
Index based production system	Records, **unalterable**

PILOT OUTCOMES #1

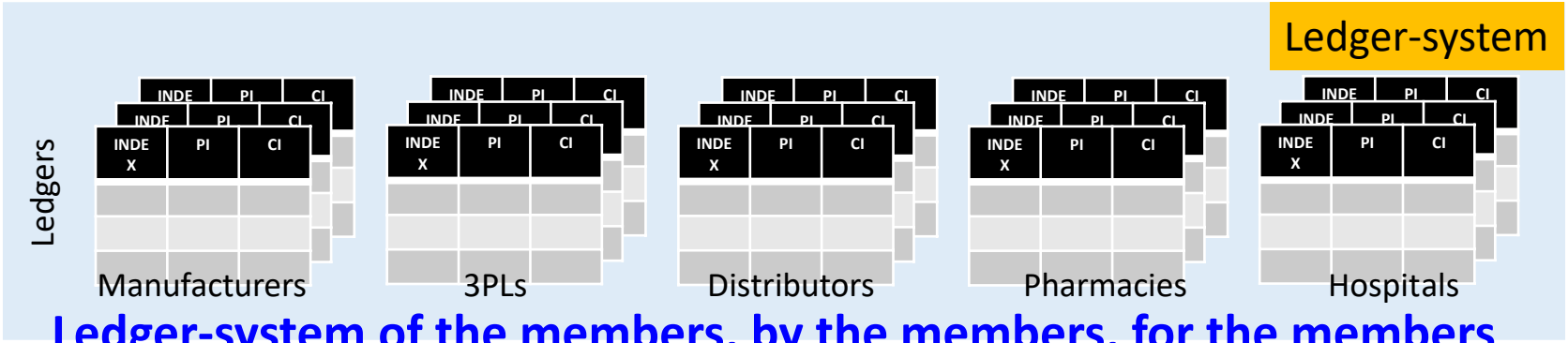
TI, TS, TH REPORTS MANAGEMENT	NOTIFICATIONS MANAGEMENT
Prompt response, No time delay	Promptly reporting of the suspects
Provides T3 reports to the stakeholders instantaneously by producing it in real time, as needed by anyone	Execute verification process across value chain each time a transaction event occurs therefore report suspects concurrently, in real time

PILOT OUTCOMES #2

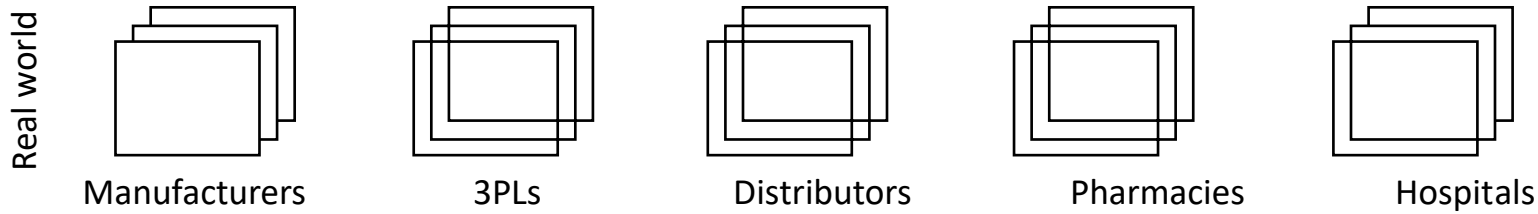
DISAGGREGATION MANAGEMENT	REPACKAGING MANAGEMENT FOR SALEABLE RETURNS
100% Accurate all time	Highly robust and foolproof
Having aggregation index-based, disaggregation results are produced with 100% accuracy	Produce SERIAL by the same index of SERIAL of original package, making it highly robust and foolproof

LEDGER-SYSTEM – AERIAL VIEW

Each stakeholder possesses its own ledger and disparate stakeholders creates an unalterable record of transactions.



Ledger-system of the members, by the members, for the members



LEDGER-SYSTEM – FUNDAMENTAL CAPABILITIES

SERIAL PRODUCTION MODULE

- Unique SERIAL for unit-level package
- Unique SERIAL for aggregates

T3 REPORT MODULE

- TI, TS, TH
- Report suspects

REPACKAGING MODULE

- SERIAL for repackaged items

PRODUCT RECALL MODULE

- One-click recall system

ENTERPRISE DATA WAREHOUSE

- For data mining, analytics, market research and decision support

LEDGER-SYSTEM – INTEGRATION PLUG-IN

REGISTRATION PROCESS

Through 2D barcode

NDC xxxxxx
SERIAL xxxxxxxxxxxx
LOT xxxx
EXPIRY xxxx

QUICK TO START

SUBCRIPTION BASED

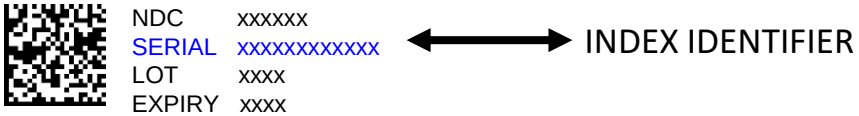
Basic plan (US $ X/ Month)		Premium plan (US $ y/ Month)	

NO INITIAL INVESTMENT

PILOT FINDINGS

Ledger-system that arranges records in the distributed ledgers which are updated in real time across value chain most efficiently, pilot findings got to be unprecedented which is,

The US pharmaceutical industry leaders select INDEX IDENTIFIER as a package identification standard and we, together, reduce **costs to the compliance to ZERO** for the stakeholders.



CONCLUSION/ RECOMMENDATIONS

For the pilot findings to materialize, our recommendations are

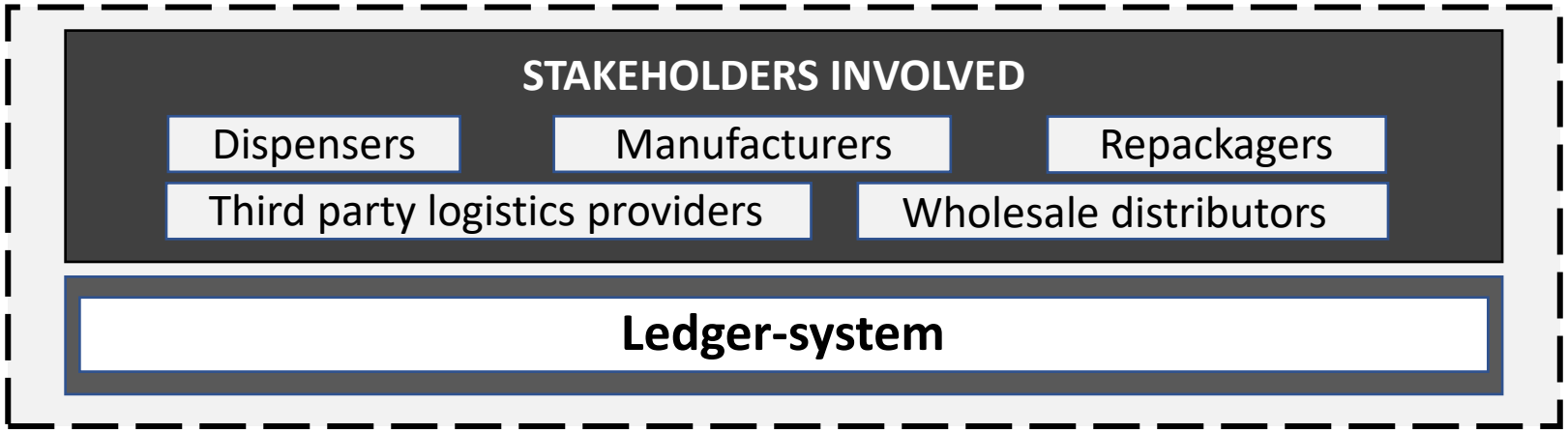
A Not-for-Profit Package Identifications Standards Organization
be created by the industry leaders of the US pharmaceutical ecosystem that develops and maintains the package identifications standards,

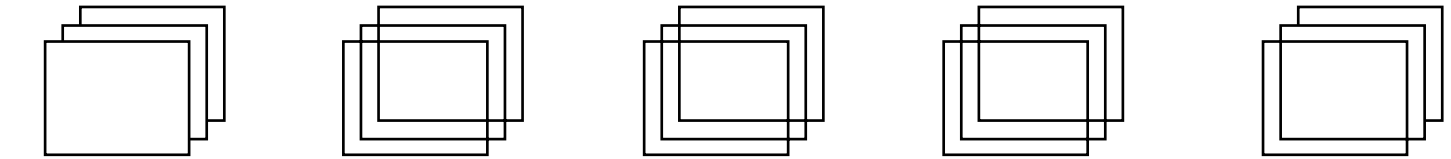
That is going to be evolved into the **Not-for-Profit Global Package Identifications Standards Organization**, across industry sectors, that enhances safety and transparency in the supply chain as well as helps automate construct of the enterprise data warehouse in the distributed ledger of its stakeholders, to be used for data mining, analytics, market research and decision supports system**.**

NEXT STEPS

Form a consortium of the US pharmaceutical ecosystem members, as the governing body for the not-for-profit organization for the Ledger-system for the 2023 DSCSA compliance.

NOT-FOR-PROFIT ORGANIZATION





Ledger-system of the members, by the members, for the members

ICON INDICES

For further details, please write to,

Anurag Saxena
Founder and CEO, ICON INDICES
anuragsaxena@iconindices.in

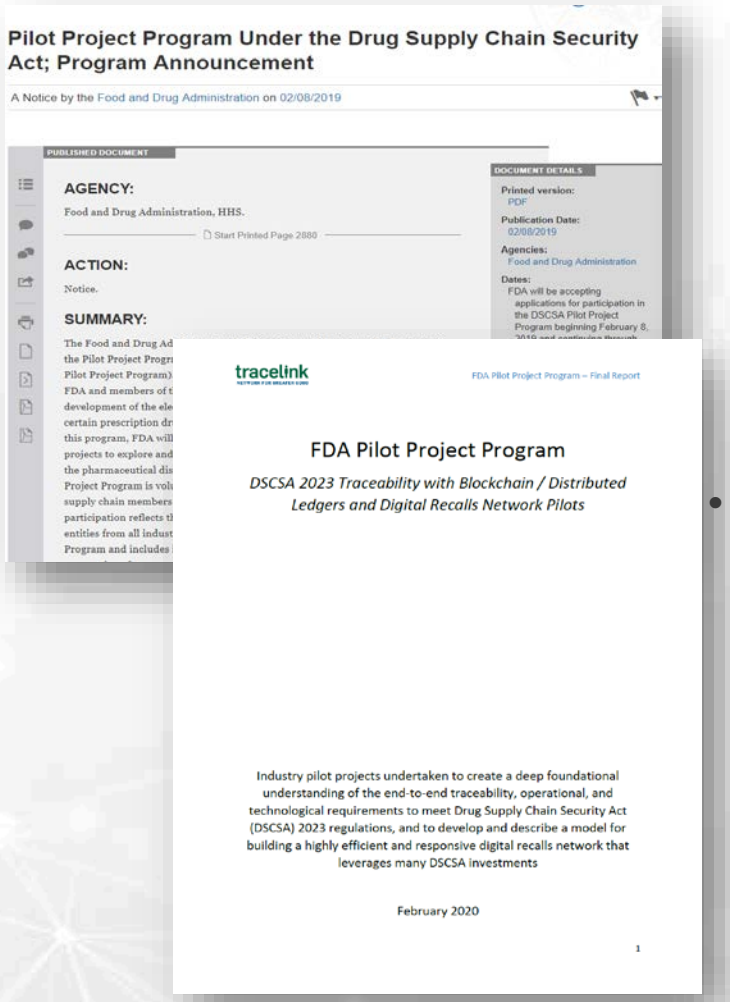
TraceLink FDA Pilot Project

DSCSA Trace Histories and Digital Recalls Network

Allan Bowyer and Amanda Bettman, TraceLink Inc.

Dec. 8, 2020

TraceLink's FDA Pilot Project Vision and Approach



- TraceLink's "2023 Pilot Project Workgroup" was an industry-led project designed to create learnings and explore alternative approaches to prepare for DSCSA's 2023 requirements and continuing to enhance the efficiency and effectiveness of the pharmaceutical supply chain.
  - ✓ Deeply analyze and describe current pharma supply chain processes for product traceability and recalls
  - ✓ Develop approaches and test requirements for a future digital supply chain infrastructure (systems, processes, data, and network interactions)
  - ✓ Identify the opportunities/benefits and challenges for enabling such a vision
  - ✓ Create a strong body of knowledge to leverage for future exploration and to help inform future discussions across the industry and with the FDA

- TraceLink's 6 month pilot project supported two dedicated workstreams to explore key pilot areas:

Trace Histories	Digital Recalls
Interoperable information sharing and "gather upon request" model for DSCSA 2023 compliance leveraging a blockchain-based tool	Electronic tracing, verification, and notification for patient safety by enabling a digital recalls network

The FDA Pilot Project was an Industry-Led Collaboration

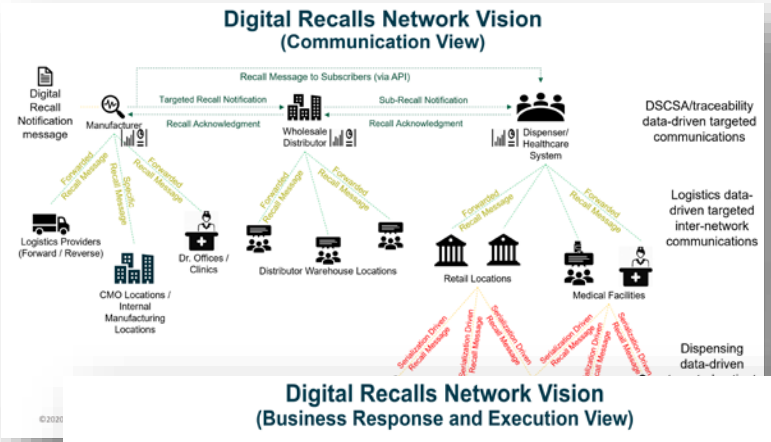
Cross-Industry, Cross-Archetype Discussion was Critical in Understanding Challenges/Opportunities

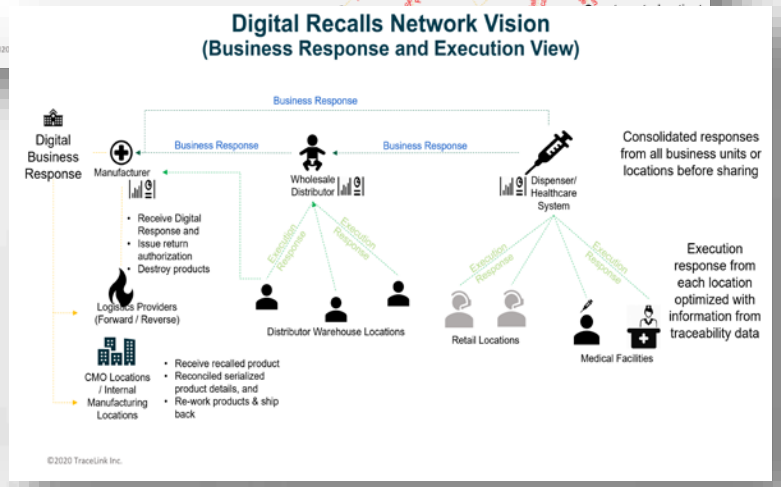
Contract Manufacturers	Pharmaceutical Companies / Repackagers	Wholesale Distributors	Dispensers	3PLs / Return Providers
Patheon, by Thermo Fisher Scientific	Pfizer	McKesson	CVS Health	PharmaLink
Sharp	Bristol Myers Squibb	Value Drug Company	Novant Health	DHL
	EMD Serono / Merck KGaA		Yale New Haven Health	Woodfield Distribution
	Novartis		Wegmans	
	Sandoz			
	Johnson & Johnson			
	Flexion Therapeutics			
	Agios Pharmaceuticals			
	Sagent Pharmaceuticals			
	Par Pharmaceuticals			
	A-S Meds			

Digital Recalls Workstream

tracelink

Digital Recalls Workstream





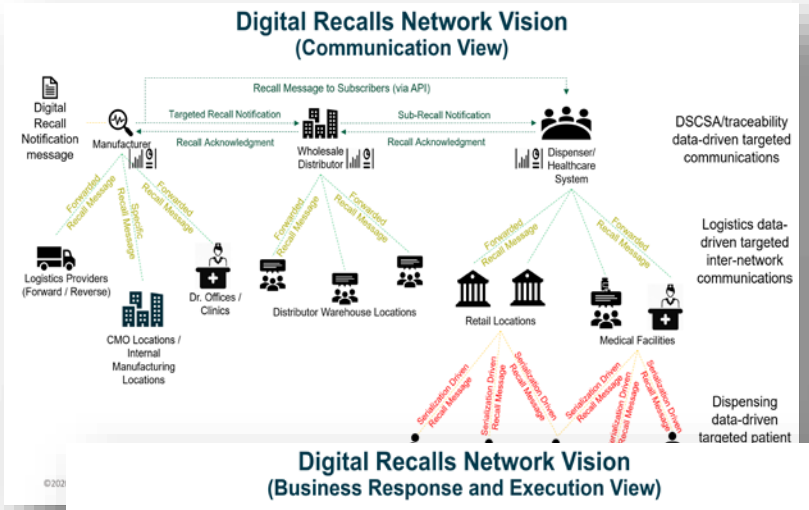
Key Objectives

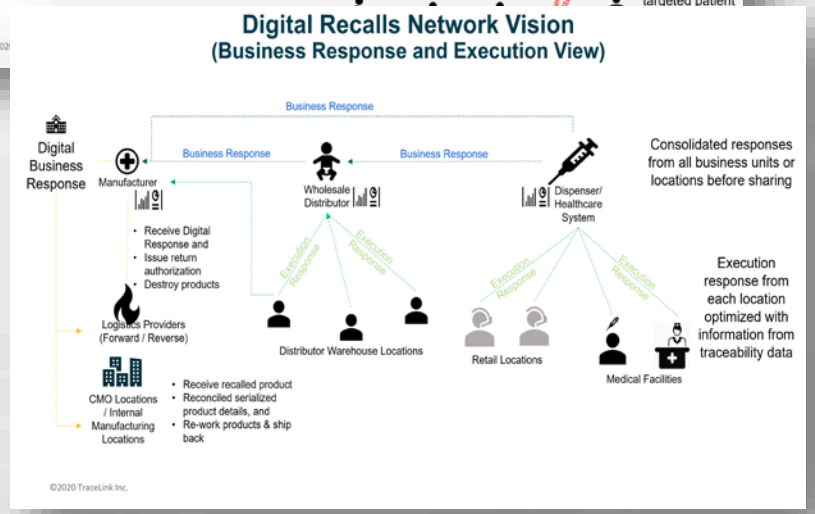
- Map As-Is Recalls Process
- Identify Current Issues, Risks, and Uncertainties
- Evaluate a Digital Recalls Network Model
- Analyze Evolution and Adoption Path

Key Outcomes

- Execution and closure of product recalls today is slower, less precise, and takes more work for all stakeholders than necessary due to:
  - Manual communications and response methods
  - Limited ability to identify and filter supply chain stakeholders with affected product
  - Delays in locating and quarantining affected product in inventory and on shelves
  - Complexities in monitoring progress and measuring closure rate
- The pilot team found opportunities to improve coordination, confidence, and performance:
  - Enable more timely and precise recall notifications and stakeholder responses
  - Enhance recalled product identification and quarantine processes in the supply chain
  - Speed the ability to remove recalled product from the supply network
  - More accurately and quickly close recall events through improving the ability to monitor recall progress

Digital Recalls Workstream





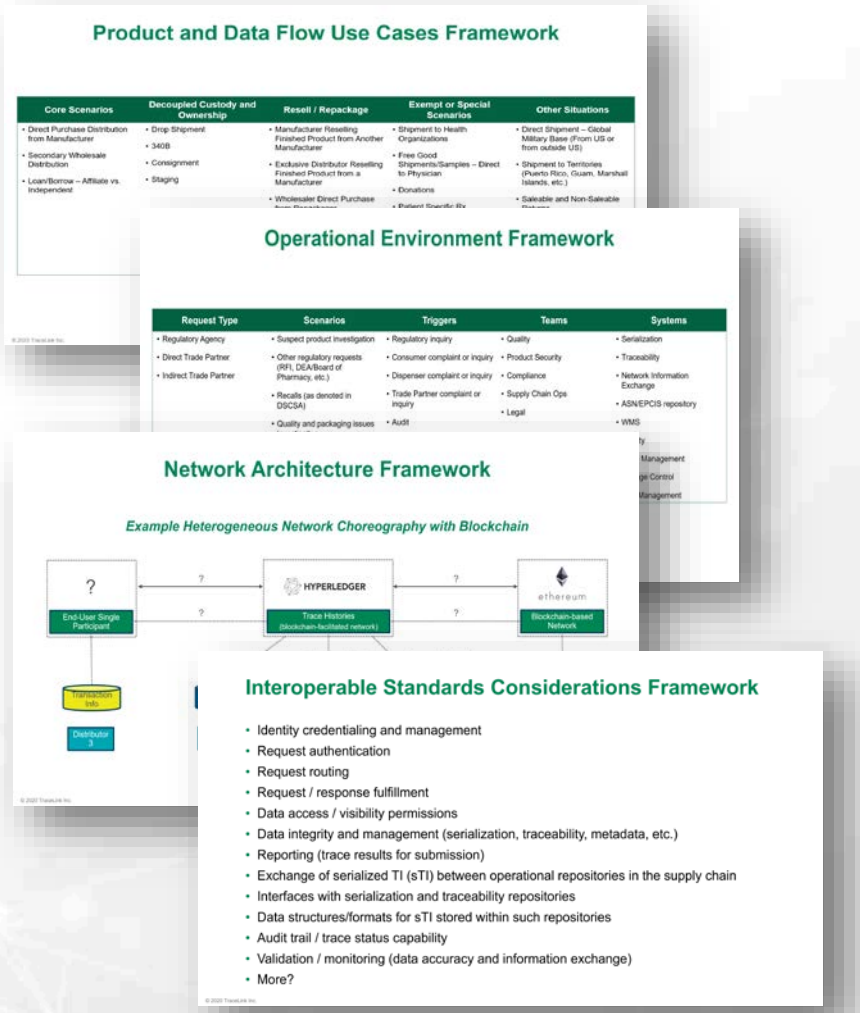
Learnings and Takeaways

- Many of the foundational building blocks to enable a digital recalls network are available today, driven by DSCSA requirements.
  - Lot-level DSCSA TI information and serialized product identifiers
  - Electronic traceability repositories across the supply chain
  - Collaborative process team environments
  - Enhanced electronic integration networks and portals driven by DSCSA requirements
- Incremental opportunities exist to implement elements of an interconnected and interoperable digital recalls network, with each providing a unique set of benefits.
  - Communication – Electronic messaging frameworks for preparation, messaging, and communication of a recall event informed by traceability data
  - Response - Supply chain stakeholder initial response and preliminary actions in a bi-directional, more collaborative workflow environment
  - Execution - Inventory and shelf sweeps, reverse logistics coordination, and execution monitoring prior to closure determination executed in coordination with traceability and serialization systems
- Operational process review and change management is critical in building confidence in the approach, coupled by engagement and alignment with FDA expectations and guidance.
- Future opportunities were also analyzed for improvements in communication to and engagement with patients in possession of recalled products.

Trace Histories Workstream

tracelink

Trace Histories Workstream



Key Objectives

Study business processes and technologies for DSCSA 2023 sTI gathering requirements, and test “gather upon request” approaches using the blockchain-based Trace Histories tool

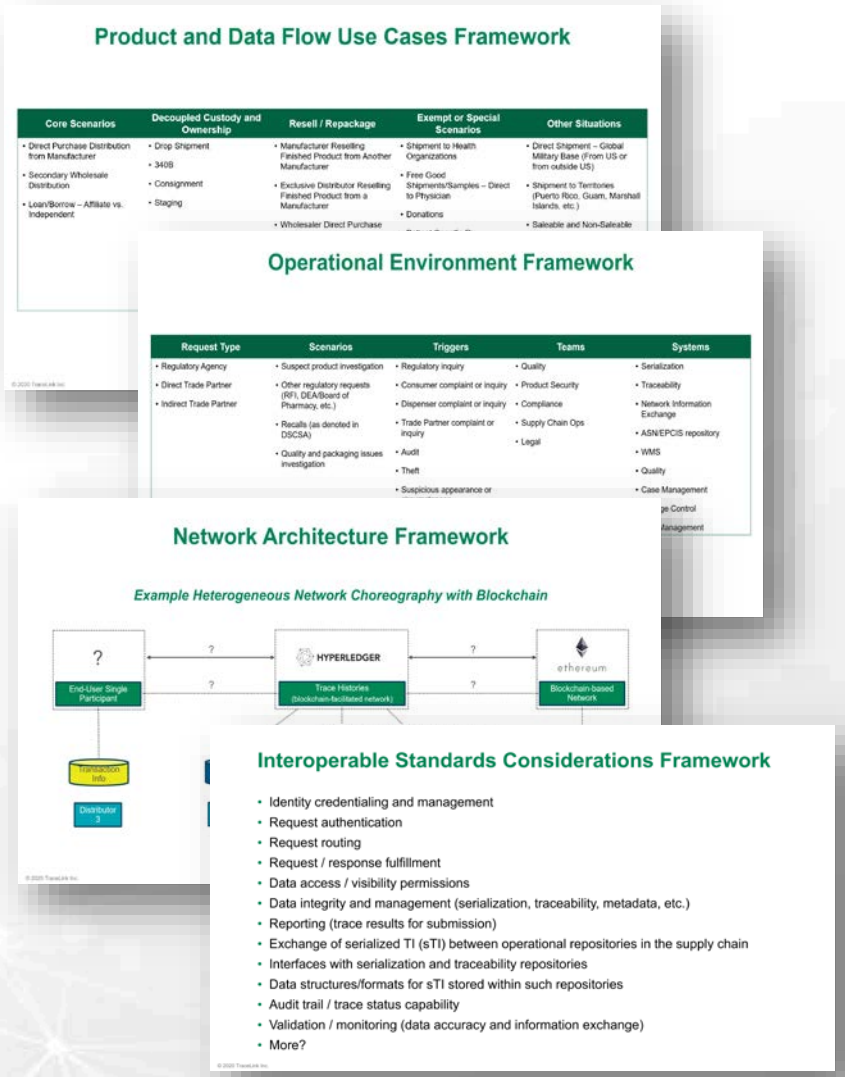
- Interoperability and Integration
- Data Management and Ownership
- Business Processes and Change Management
- Technical Infrastructure

Key Outcomes

Frameworks for DSCSA 2023 product traceability process and solution value analysis

- Product and data flow use cases highlighting complex, diverse product movement
- Operational environment analyses describing complex process and system interactions
- Network architecture approaches denoting options and considerations for technologies including distributed ledger / blockchain methods
- Interoperability considerations and standards requirements to embrace and manage the heterogeneous nature of the supply chain, its stakeholders, and its systems

Trace Histories Workstream



Learnings and Takeaways

- The industry continues to build an understanding and appreciation of the full complexity and diversity of the pharma supply chain – product and data flows, processes, inter-company orchestration.
- The change to this network to enable unit-level traceability and verification (where required) of product across the supply chain will be immense.
  - Russia, EU FMD and DSCSA VRS provide initial indications of the planning, implementation, and on-going operational support required.
- There won't be a single "big-bang" technology or system which solves everything.
- Expect the end result to be heterogeneous and highly diverse, making open interoperability and alignment on expectations across stakeholders a critical success factor.
- Many potential technologies or solution approaches, including blockchain-based systems, do demonstrate significant promise but still need more time to be fully understood and tested.
- Equally critical are the adjustment and maturation of multi-enterprise processes, internal SOPs, etc. to manage serialized product operations and traceability in today's high volume, increasingly complex product supply chain.
- Future success mandates that we build an agile digital supply chain
  - Embracing the full diversity of the end-to-end supply chain
  - Resilient in managing challenges of data integrity, process exceptions, and unexpected daily issues (such as pandemic responses).

Questions?

For a copy of the final report or to discuss the pilots in more depth:

Allan Bowyer
community@tracelink.com

tracelink

Interoperable DSCSA Review with SDxS

Dec 2020

Antitrust Statement

The purpose of this association is to explore avenues of mutual interest and cooperation in public policy and to contribute to the Optimal Solution Interoperable DSCSA FDA Pilot. It is important to recognize that these activities are subject to certain legal limits imposed by state and federal antitrust laws. One central concern of these laws is with combinations or agreements in restraint of trade whereby competition is reduced by design. Business people generally are cognizant of the restrictions on price fixing imposed by the law. In addition, there are many other areas in which legal implications are raised. For example, agreements to reduce prices, standardize discounts, divide territorial markets or customers, or to promote group boycotts are illegal. Consequently, in the course of all team activities, discussions among members involving pricing, sale terms, territories, production or other aspects of competition, must be avoided. In the event any member ever feels that the course of association activities or statements or actions in association meetings is headed into such an area, participants should raise the issue immediately so that further discussion of such matters can be suspended pending receipt of advice from council that the topics addressed do not give rise to antitrust problems.

DSCSA Optimal Solutions Team

T-Systems

Transparent

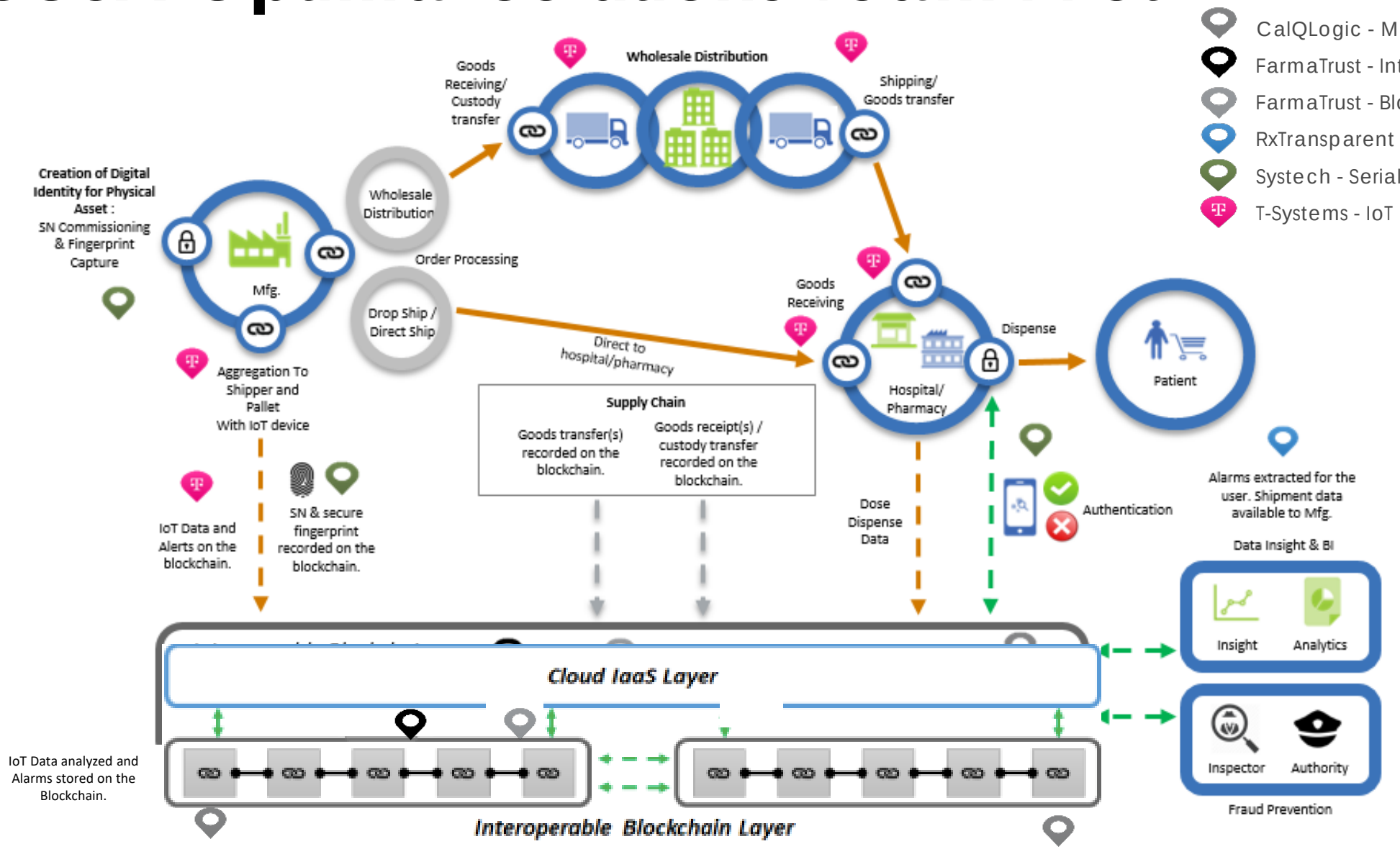
SYSTECH™

CalQLogic

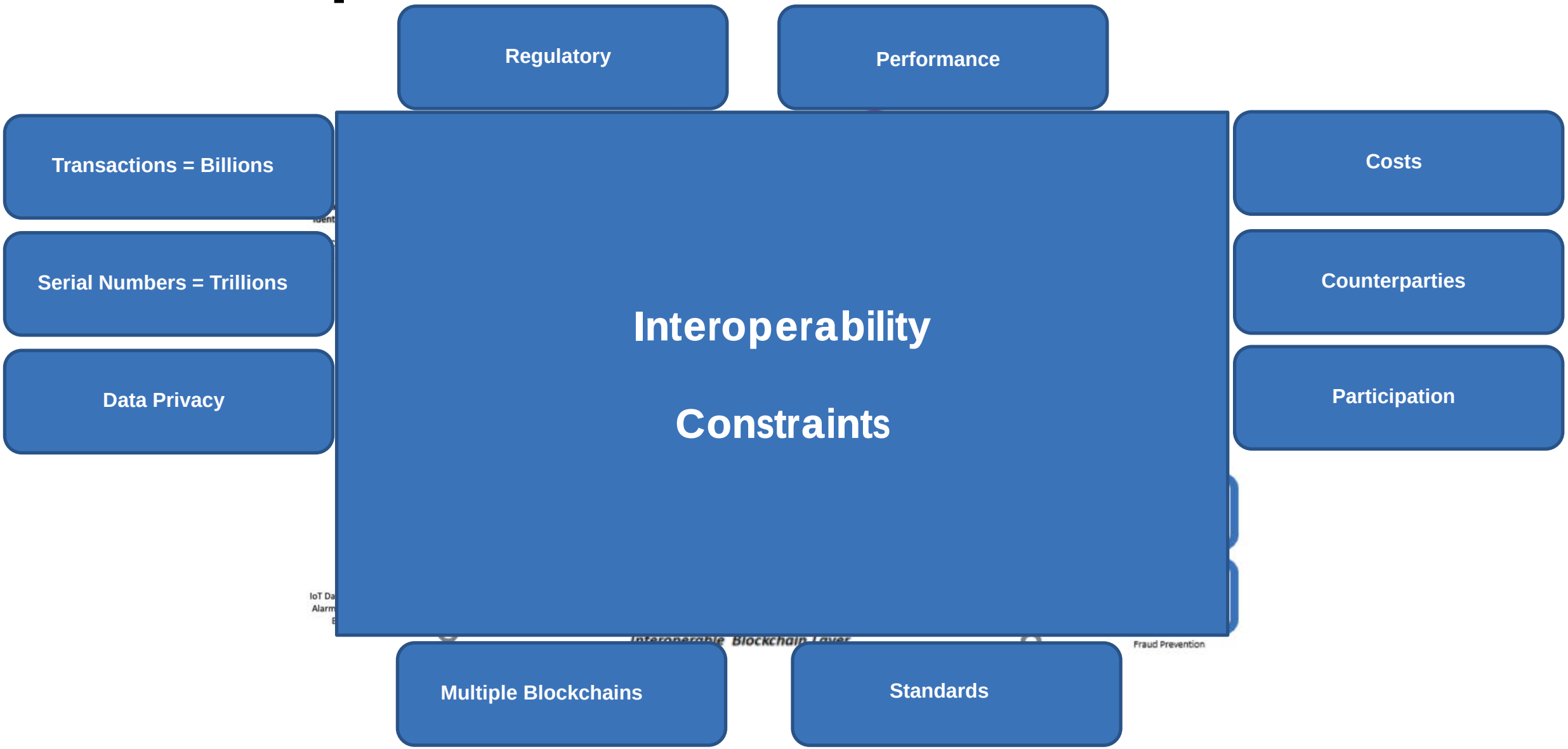
FarmaTrust

dyadis

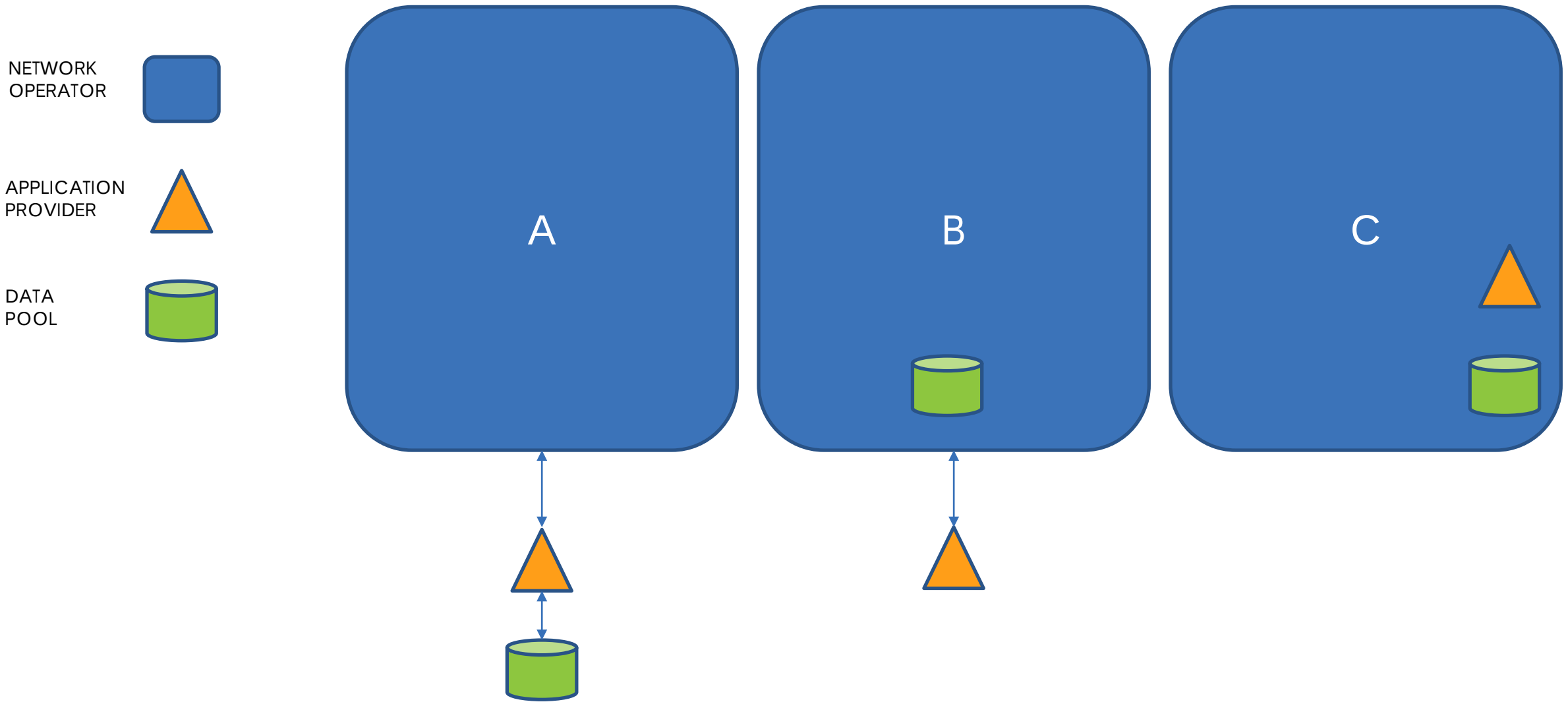
DSCSA Optimal Solutions Team Pilot



DSCSA Optimal Solutions



Solution Provider [Service Offerings]



SDxS – [What is it?]

Serialized Distributed Extensibility Service

A lightweight, low-cost, scalable, distributed, interoperable system that facilitates safe, secure, effective data exchange between pharmaceutical supply chain trading partners.

SDxS – How We Got Here

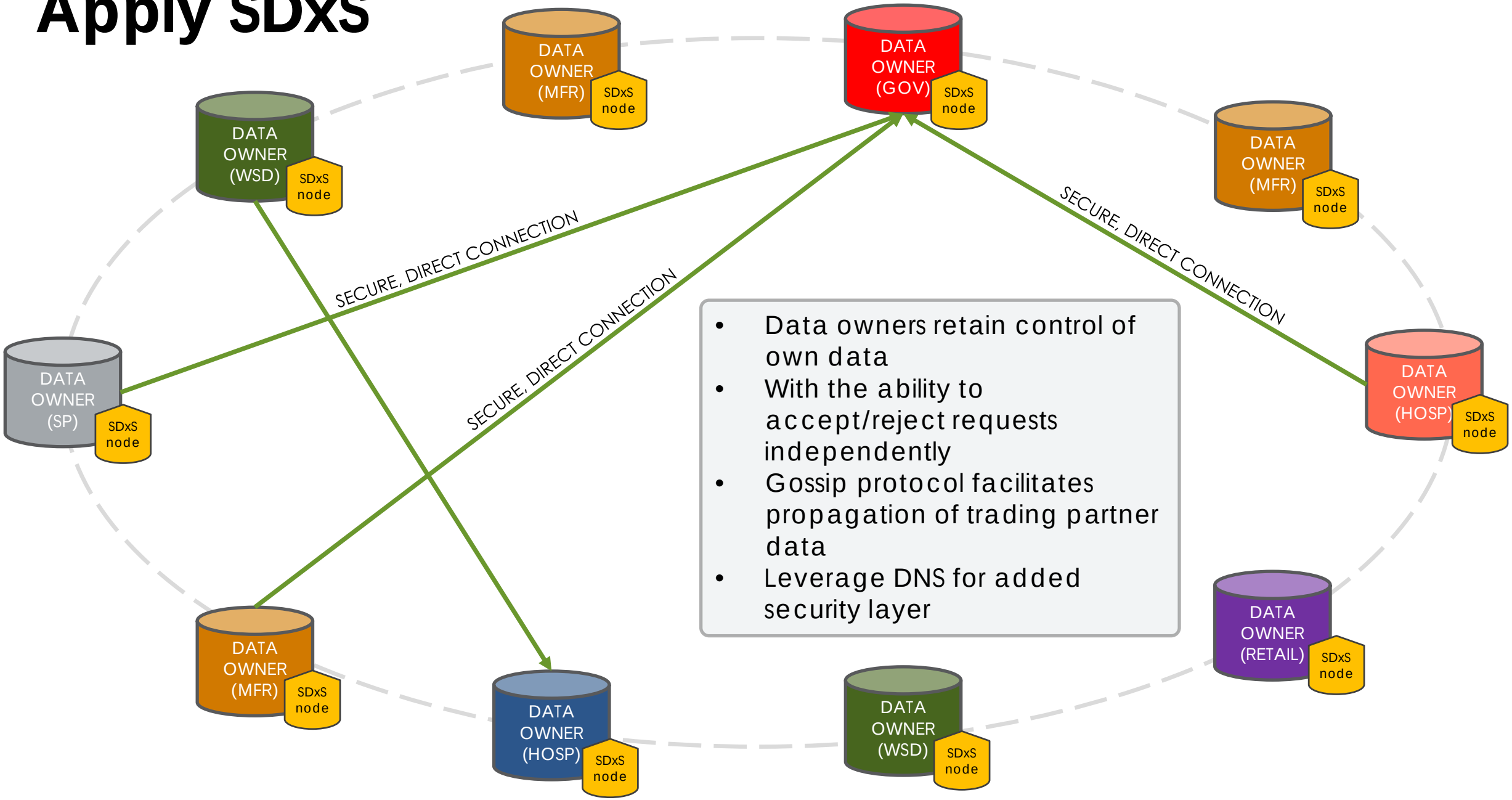
Design Decisions

- Leverage Existing Technologies
- Cryptography
- DNS
- Distributed Replication
  - Gossip Protocol
  - Avoid Centralization
- Open Source
- Lightweight

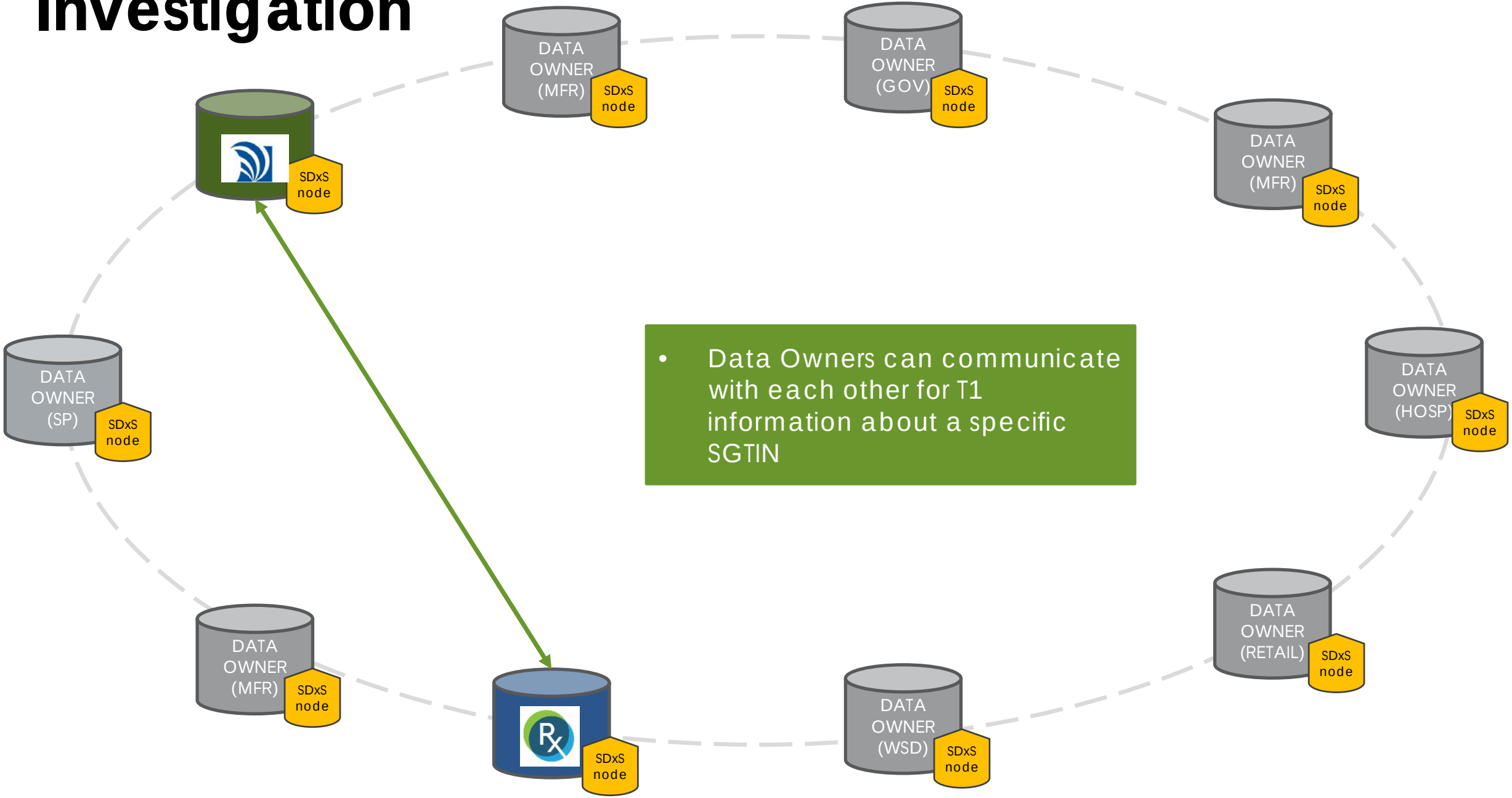
Constraints

- Data Privacy & Security
- Performance
- Scalability
  - Transaction Volume
- Cost
  - Entry
  - Operation

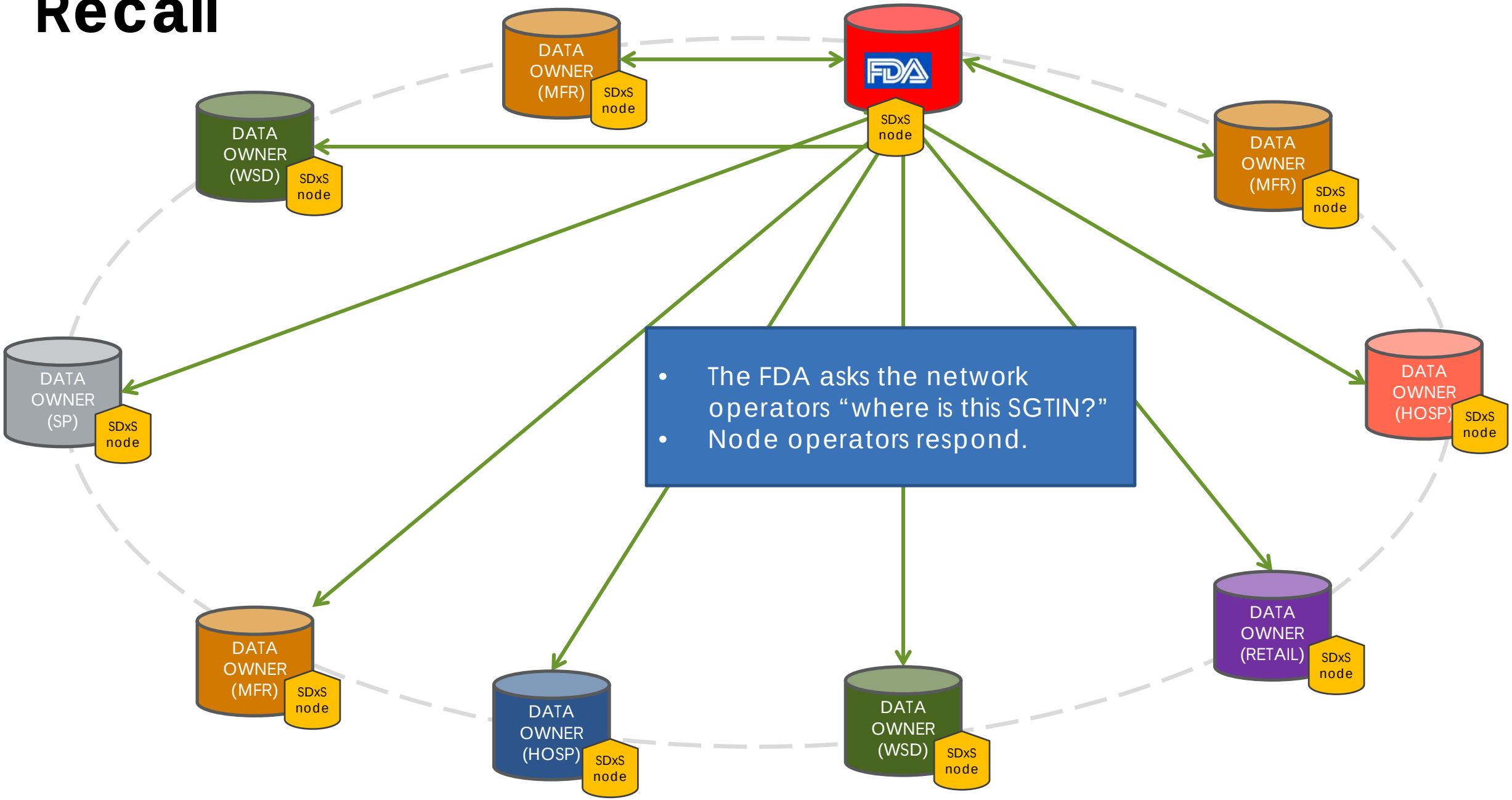
Apply SDxS


DATA OWNER (MFR)
SDxS node
DATA OWNER (GOV)
SDxS node
DATA OWNER (WSD)
SDxS node
DATA OWNER (MFR)
SDxS node
SECURE, DIRECT CONNECTION
SECURE, DIRECT CONNECTION
SECURE, DIRECT CONNECTION
DATA OWNER (SP)
SDxS node
DATA OWNER (HOSP)
SDxS node
DATA OWNER (MFR)
SDxS node
DATA OWNER (HOSP)
SDxS node
DATA OWNER (WSD)
SDxS node
DATA OWNER (RETAIL)
SDxS node
• Data owners retain control of own data
• With the ability to accept/reject requests independently
• Gossip protocol facilitates propagation of trading partner data
• Leverage DNS for added security layer

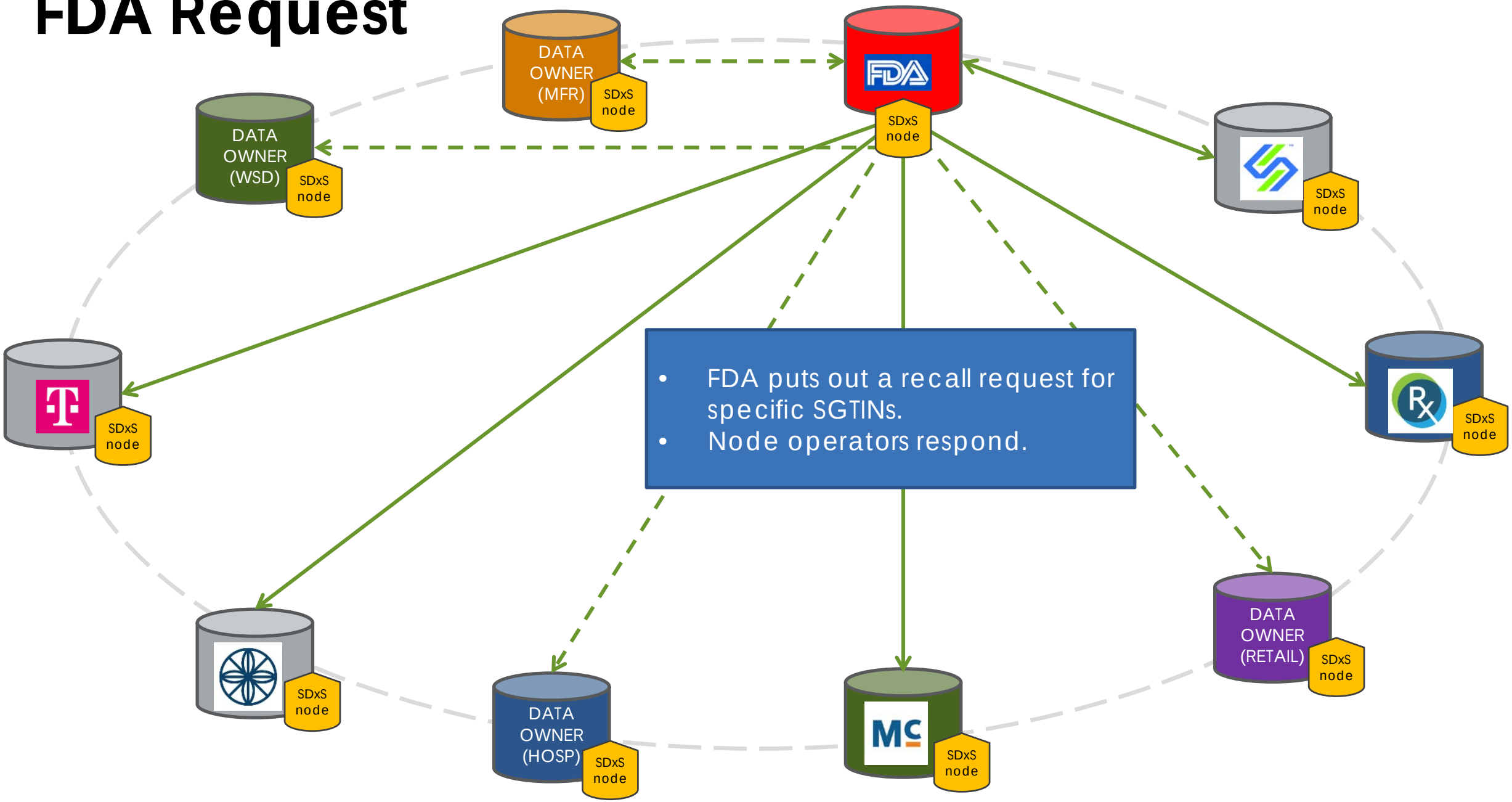
Investigation



Recall


DATA OWNER (MFR)
SDxS node
FDA
SDxS node
DATA OWNER (WSD)
SDxS node
DATA OWNER (MFR)
SDxS node
DATA OWNER (SP)
SDxS node
• The FDA asks the network operators “where is this SGTIN?”
• Node operators respond.
DATA OWNER (HOSP)
SDxS node
DATA OWNER (MFR)
SDxS node
DATA OWNER (HOSP)
SDxS node
DATA OWNER (WSD)
SDxS node
DATA OWNER (RETAIL)
SDxS node

FDA Request


DATA OWNER (MFR)
SDxS node
FDA
SDxS node
DATA OWNER (WSD)
SDxS node
SDxS node
SDxS node
• FDA puts out a recall request for specific SGTINs.
• Node operators respond.
SDxS node
SDxS node
DATA OWNER (RETAIL)
SDxS node
DATA OWNER (HOSP)
SDxS node
SDxS node

Questions?

Product Identifier Verifications by a CMO on behalf of MAH

Pilot Results ,Dec 8th 2020

Arthi Nagaraj

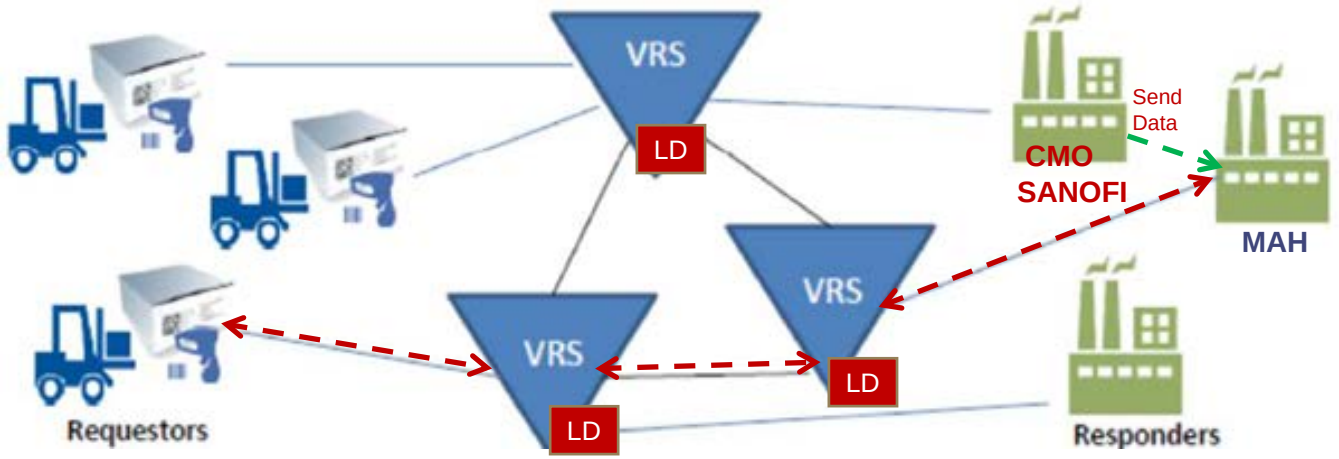
Agenda

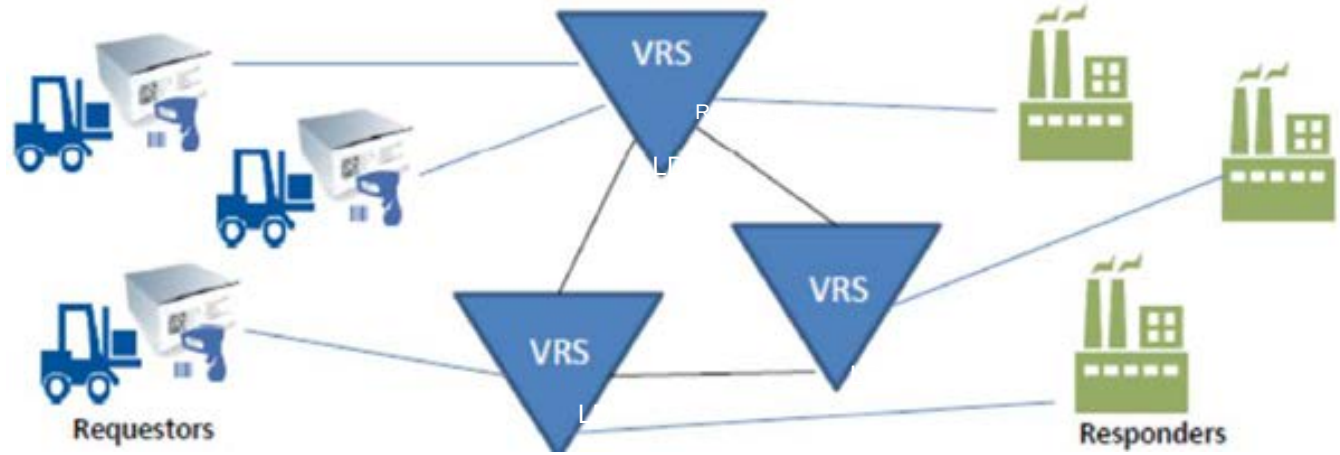
- Objective and Introduction
- Pilot Project Participants
- Pilot Project Outcomes
- Pilot Project Conclusions
- Pilot Project Recommendations

Objective and Introduction

Traditional

All SNs in MAH VRS Repository





Pilot Project Participants

Company	Type	Contact	Size: Number of employees
Sanofi	Manufacturer	Arthi Nagaraj Arthi.Nagaraj@sanofi.com Reid Graves Reid.Graves@sanofi.com	110,000
McKesson	Wholesale Distributor	Scott Mooney Scott.Mooney@McKesson.com Vinod Vedire Vinod.Vedire@McKesson.com	80,000
Advanz Pharma	Virtual Manufacturer	Chris Humphrey Chris.Humphrey@advanzpharma.com	400
Adents	Service Provider	Saad Achouri sachouri@adents.com	100

Pilot Project Outcomes

- CMO and MAH DSCSA responsibility only known to the 2 parties
- Dependence on solution providers during investigations
  - Challenges on different terminologies and interfaces used by solution providers
  - Significant time needed to investigate even in a small pilot with 3 solution providers, 1 wholesale distributor & 2 manufacturers
- This process in effect tested the Mergers and Acquisitions logic.

Pilot Project Conclusions

- Interoperability and delegation of verification is possible between the Contract Manufacturer (CMO) and the Marketing Authorization Holder (MAH) using the VRS network.
- Demonstrated that delegation is effective
- Parties involved in delegation need a clear understanding of who is responsible for what

Pilot Project Recommendations

- **Set up an agreement on who is responsible to load the LD**
  - If GTIN is initially pointing one entity (MAH) and is then delegated to the CMO, updating the Look up directory with the GTIN pointing to the CMO did not automatically update the network
- **Understand the HDA Specifications**
  - The start and end date fields in the LD entry by the CMO overlapped with the dates in the LD entry by the MAH. Due to this, the LD update by the CMO was rejected
- **Standardize key functionalities**
  - Different terminologies and system functionalities used to achieve the same action between service providers cause confusion when debugging an issue
- **Understand how the ERP or serialization system master data ties to the VRS master data**
  - Production as a CMO for a MAH may mean having the GLN of the MAH in internal serialization systems. Depending on system connectivity and data flows, you may end up with a response to the VRS request with the CMO GLN instead of the MAH

Pilot Project Recommendations

- **Capture error messages by intermediate systems**
  - In a test performed, the manufacturer report showed that the verification was false (as expected) but the distributor received an error
- **Alignment on who triggers a communication when there is a false verification or an error**
- **Perform a complete network test prior to “go-live”**
  - Perform a full test in the production environment with provisions/discretions on triggering a suspect product. A full test can help bring other issues to the surface, including which party raises the error

THANK YOU

SANOFI

Appendix

Lexicon

Terms	Description
MAH	Marketing Authorization Holder
CMO	Contract Manufacturer
PI	Product Identifier. This consists of the GTIN, Serial number, Lot and Expiry
GTIN	Global Trade Identification Number. This is part of the GS1 standards that can be used by companies to identify their Trade items
DSCSA	Drug Supply Chain Security Act
VRS	Verification Router Service. This is interoperable solution used to primarily address DSCSA verification requirements for the Saleable returns' regulation
HDA	Healthcare Distribution Alliance. HDA is a national organization representing primary pharmaceutical distributors
LD	Lookup Directory. This is akin to a phonebook where manufacturers store their products' GTINs so that the VRS knows to route the verification request to the correct manufacturer's repository of product identifiers
GLN	Global Location Number. This is part of the GS1 standards that can be used by companies to identify their locations
Pilot	A small-scale study to evaluate feasibility of a concept

The Global Language of Business

Healthcare

DSCSA Pilot Project readiness results

How the industry is preparing for DSCSA Interoperability

Peter Sturtevant, Sr. Director Community Engagement, GS1 US

Antitrust Caution

GS1 US is committed to complying fully with antitrust laws.

We ask and expect everyone to refrain from discussing prices, margins, discounts, suppliers, the timing of price changes, marketing or product plans, or other competitively sensitive topics.

If anyone has concerns about the propriety of a discussion, please inform a GS1 US® representative as soon as possible.

Please remember to make your own business decisions and that all GS1 Standards are voluntary and not mandatory.

Please review the complete GS1 US antitrust policy at:
www.gs1us.org/gs1-us-antitrust-compliance-policy

DSCSA Pilot Project - Goals/Objectives:

- Measure year over year progress of industry preparedness for DSCSA, in terms of pharmaceutical manufacturers' serializing their packages and homogeneous cases.

- Expand the scope of analysis to include the 2023 requirements and quantify impacts of readiness in these areas.

- At a high level, objectives of barcode testing include examination of:
  - Readability of a barcode either printed or affixed to product, including impact of environmental and human factors.
  - Application of linear barcode and 2D barcode on product
  - Distinguishing which barcode to read/use

Pilot Participants

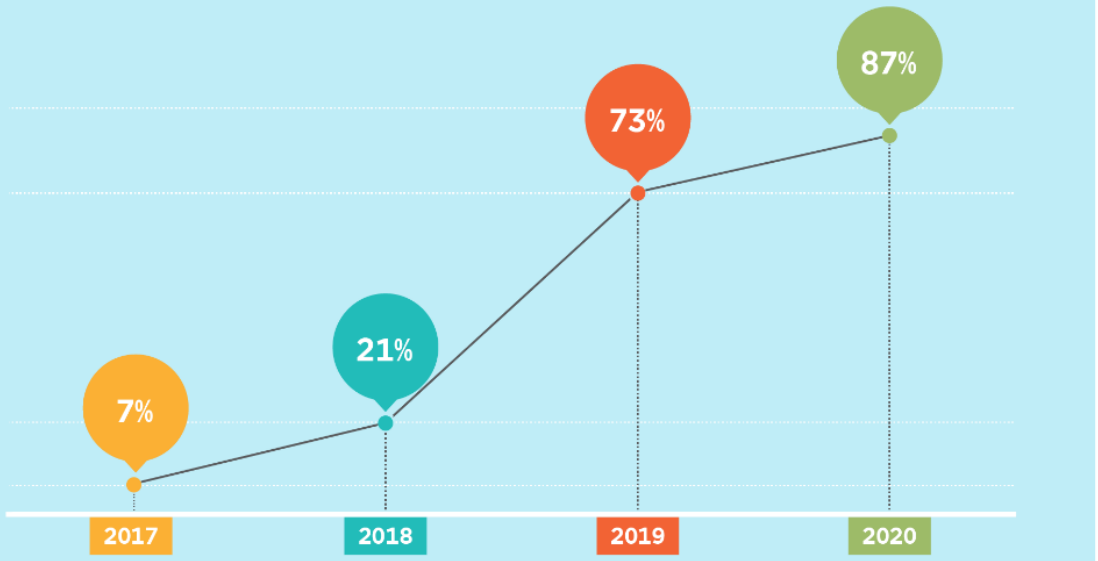
- **AmerisourceBergen**
  - Wholesale Distributor – Specialty Products – Packages
- **Cardinal Health**
  - Wholesale Distributor – National Logistics Center – Homogeneous Cases
- **McKesson Corporation**
  - Wholesale Distributor - core Rx Products - Packages
- **GS1 US**
  - Recognized International Standards body

Pilot Project Key Outcomes

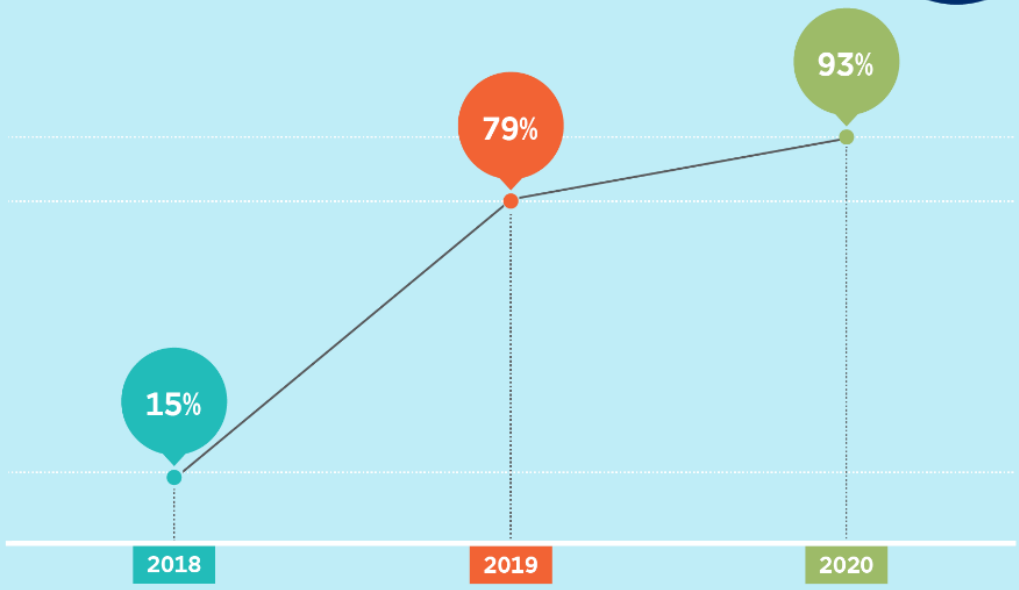
- The Big 3 wholesale distributors and scanned over **51k barcodes** in their distribution centers.
- AmerisourceBergen and McKesson, conducted a fourth series of barcode assessments of the "**packages**" to track year over year, progress on serialization of 2D barcodes with the 4 Identifiers.
- Cardinal Health conducted the barcode assessment of "**homogeneous cases**" from pharmaceutical manufacturers with **linear or 2D barcodes** for the 3rd year.
- Scans of **packages** and **homogeneous cases** revealed more than **20% improvement** in serialized products since 2019*

Excellent Progress (packages & homogeneous cases)

Progression of Serialized Products With a GS1 DataMatrix Containing Four Application Identifiers



Specialty Products at AmerisourceBergen and Rx Products at McKesson



Homogeneous Cases at Cardinal Health

Source: 2020 GS1 US Barcode Assessment

Significant sample

32,500

barcodes scanned

2D and linear barcodes on 10,900 cases from 206 manufacturers

Homogeneous Cases
at Cardinal Health

3,000

packages scanned

representing 255 manufacturers

Specialty Products
at AmerisourceBergen

19,000

packages scanned

representing 528 manufacturers

Rx Products
at McKesson

Source: 2020 GS1 US Barcode Assessment

2020 Results - Driving to 100%

Progress in 2D Barcode Adoption With DSCSA Requirements | 2020

Packages and Cases Scanned

21,169
Rx and Specialty Products 2020

10,900
Homogeneous Cases 2020

Readable Barcodes With All Four DSCSA Data Elements

87%
Rx and Specialty Products 2020

93%
Homogeneous Cases 2020
(readable 2D barcodes)

Source: AmerisourceBergen, Cardinal Health, and McKesson Barcode Assessments

Package Results past Four Years

Progress in 2D Barcode Adoption With DSCSA Requirements

Specialty Products at AmerisourceBergen and Rx Products at McKesson

2017-2020

Packages Scanned

Packages 2017
16,618

Packages 2018
21,209

Packages 2019
17,859

Packages 2020
21,169

Readable Barcodes With All Four DSCSA Data Elements

Packages 2017
7%

Packages 2018
21%

Packages 2019
73%

Packages 2020
87%

Source: AmerisourceBergen, Cardinal Health, and McKesson Barcode Assessments

Homogeneous Cases year over year growth

Progress in 2D Barcode Adoption With DSCSA Requirements

Homogeneous Cases at Cardinal Health

2018-2020

Cases Scanned

Cases 2018
6,481

Cases 2019
7,996

Cases 2020
10,900

Readable Barcodes With All Four DSCSA Data Elements

Cases 2018
15%

Cases 2019
79%

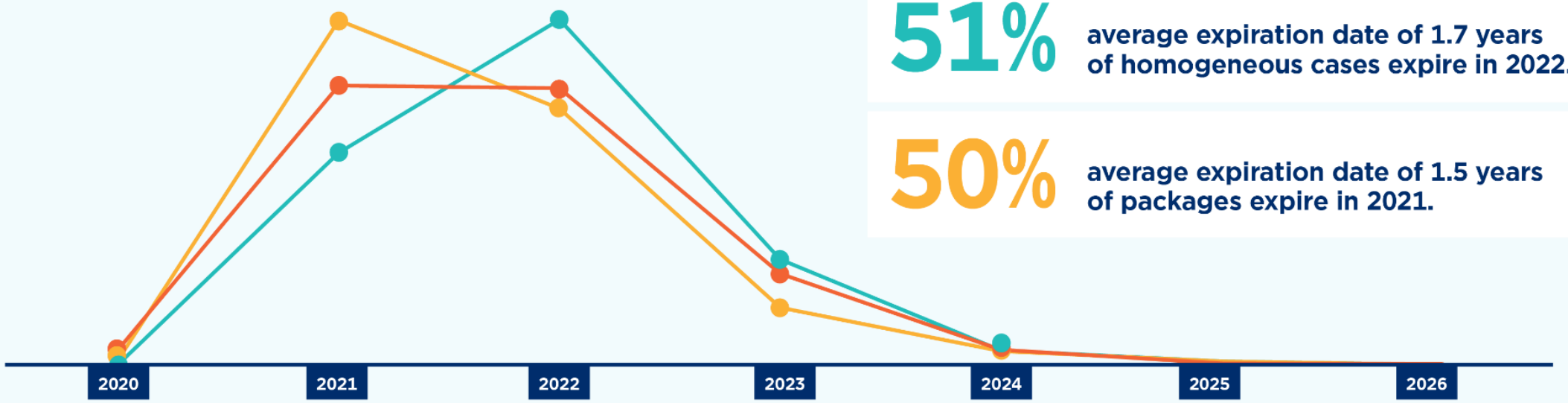
Cases 2020
93%

Source: AmerisourceBergen, Cardinal Health, and McKesson Barcode Assessments

2020 **Expiration Date** Analysis

Barcode Assessment Expiration Years

2020



51% average expiration date of 1.7 years of homogeneous cases expire in 2022.

50% average expiration date of 1.5 years of packages expire in 2021.

Specialty Products at AmerisourceBergen 1.5 years

Rx Products at McKesson 1.6 years

Homogeneous Cases at Cardinal Health 1.7 years

Source: 2020 GS1 US Barcode Assessment

00 Expiration dates

- Nearly two percent of the products had a “00” day in the expiration date.
- The industry is preparing for electronic exchange of event data for interoperability between trading partners with Electronic Product Code Information System (EPCIS).
- “The double zero is still a challenge,” says Mooney. “It does not fit the data format for the EPCIS, so we discourage it’s use in the barcode itself.
- All three elements specify an identical year, month, and non-zero day
  - EPCIS: `<cbvmda:itemExpirationDate>2023-03-15</cbvmda:itemExpirationDate>`
  - Barcode: (17)230315
  - Human Readable: 2023-03-15

Better Barcode Quality

- Legibility of barcodes on packages increased.
- In past years, certain barcodes on packages would not scan, since they were applied on shiny surfaces or were printed in inappropriate colors.

"These kinds of problems were nearly absent this year. To the best of my knowledge, we had only two instances where we experienced barcodes in difficult-to-read colors or surfaces. With the quality barcodes, we were able to scan noticeably quicker."

Scott Mooney, VP of Distribution Operations, Supply Chain Assurance, McKesson

Color: Symbol Bars and Spaces

- **Bars:**
  - Black is best
  - Next best dark blue or green
  - No red, orange, or yellow bars

Spaces:

White is best

Next best red and orange

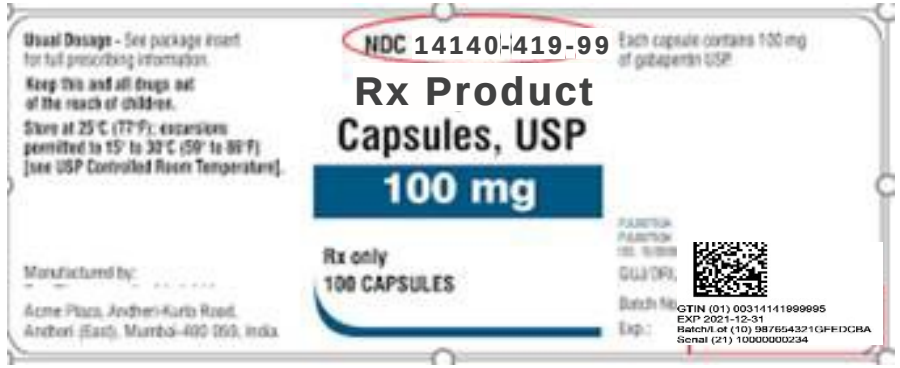
No blacks, dark blues, or dark greens

BARS		
BEST	NEXT BEST	NEXT BEST
		
NO	NO	NO
		

SPACES		
BEST	NEXT BEST	NEXT BEST
		
NO	NO	NO
		

NDC and GS1 DataMatrix on the Label

- NDC needs to be printed on the label in a human readable form, with the three components including dashes. The National Drug Code* is a unique 10-digit, 3-segment numeric identifier; Labeler, Product code, and Package code with appropriate white space.



2D Barcode

GS1 DataMatrix

GTIN (01) 00314140999996
EXP 2021-12-31
Batch/Lot (10) 987654321GFEDCBA
Serial (21) 10000000234

*Source: https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory

Vision Towards the Future

"With full traceability planned for 2023, the ability to track and communicate across the supply chain will be down to the unique lowest saleable unit. This has never been available before and will unlock value and increase accuracy and specificity to new levels."

Ameer Ali, Senior Director, Manufacturer Operations, AmerisourceBergen

DSCSA Pilot Project Program

Participant Results (1)

Program Participant/Speaker *(All partnering entities are not listed)*	**Pilot Project**
Partnership for DSCSA Governance (PDG)/Matthew Price	DSCSA Governance Processes
ICON INDICES Anurag Saxena	Enterprise Serialization Architecture of Point-To-Point Network System
Tracelink Allan Bowyer	DSCSA Traceability with Distributed Ledgers and Digital Recalls Project Proposal
The Optimal Solution Dwight de Vera	The Optimal Solution a Federated Approach to Designing the Interoperable DSCSA
Sanofi Arthi Nagaraj	Product Identifier Verifications by a Contract Manufacturing Organization on behalf of a Manufacturer Authorization Holder
GS1 US Peter Sturtevant	Barcode Readability for DSCSA 2023 Interoperability

Participant Panel Q&A

- Please type in your question for the panel into the chat box.
- FDA will select and direct questions to the panel.